DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: neotame
Docket No.: 03E-0257

JUN 23 2004

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The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,480,668, filed by The NutraSweet Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for neotame, the food additive claimed by the patent.

The total length of the regulatory review period for neotame is 3,143 days. Of this time, 1,503 days occurred during the testing phase and 1,640 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a major health or environmental effects test ("test") involving this food additive product was begun: December 2, 1993.

   FDA has verified the applicant's claim that the test was begun on December 2, 1993.

2. The date the petition requesting the issuance of a regulation for use of the additive ("petition") was initially submitted with respect to the food additive product under section 409 of the Federal Food, Drug and Cosmetic Act: January 12, 1998.

   The applicant claims December 17, 1997, as the date the petition for neotame was initially submitted; however, FDA records indicate that the petition was submitted on January 12, 1998.

3. The date the petition became effective: July 9, 2002.

   FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on July 9, 2002.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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